THE UNIVERSITY OF MEMPHIS

Institutional Review Board
315 Administration Building
Memphis, TN 38152-3370
Office: 301.678.2705
Fax: 901.678.2199
irb@memphis.edu

Initial Review Request Guidelines

General Directions

The purpose of this document is to lead you, the researcher, through the steps to a successful submission of an IRB application, also called an Initial Review Request. The Initial Review Request is required for all studies involving human subjects, including Exempt Research, Non-Exempt Research, and Secondary Analysis of Existing of Data. The sections required for different study types are as follows:

- Exempt Research - complete sections 1 through 3 and 5 through 16,
- Non-Exempt research - complete sections 1 through 3 and 5 through 16
- Secondary Analysis of Existing Data - complete sections 1 through 6 and 13 through 15.

Provide answers that are clear, complete and succinct. Do not simply attach sections of research proposals or grant applicants. Avoid unnecessary jargon and define terms that are specific to your discipline, but not likely known to a competent reviewer. Finally, please provide a complete application. Unless otherwise noted, all sections of the application must be completed. This application must be complete before the IRB reviews the request.

Please use the IRB glossary for clarification of terms used in these guidelines. The form to use for your Initial Review Request can be found at http://www.memphis.edu/rsp/compliance/irb_forms.php

Directions by Section

1. BASIC INFORMATION

a) *Lead Investigator ("LI")*. This section refers to the person who has overall responsibilities for the study. It is also the person who has primary responsibility for communicating to the IRB. Official IRB correspondence will be sent only in writing via e-mail to University sponsored e-mail accounts of the LI, Contact person, and faculty advisor where applicable.

b) *Contact Person*. For some projects the Lead Investigator will have a person who will manage correspondence. This person might be an administrative assistant or lab manager. Messages to the Lead Investigator will be sent via this contact person.

c) *Faculty Advisor*. Student investigators must identify a faculty advisor. This advisor is responsible to review and approve the Initial Review Request before it is submitted to the IRB. Faculty advisors are required to have a current CITI certification on file with the IRB prior to approving a student's submission. This section is only required if the lead investigator is a student.

d) *Study Information*. The lead investigator must provide an estimate of the likely number of participants required to address the project's questions. Listing co-investigators is optional. A co-investigator is considered someone who shares responsibility for the study as a whole. Any person who needs to listed on the IRB's approval letter needs should be here as a co-investigator.

e) *Affirmations.* Read carefully. Questions should be addressed to the IRB via irb@memphis.edu.

2. PURPOSE OF THE STUDY

a) *Study Goal*. Provide a concise statement of the study hypothesis(es) or goal(s).

b) *Literature review*. Briefly describe how the pertinent body of literature supports the study goal. Include citations and references.

c) *Possible contribution*. Describe the potential benefits of the proposed research study to the literature.

3. METHODS AND PROCEDURES

a) Study design. Provide a summary statement of the design methodology used. For example, stating that the study is a randomized clinical trial using a double blind procedure with a placebo control. Another example would be a reanalysis of de-identified archival data.

b) *Materials.* Provide a concise description of all special equipment, instruments, or measures in this section. Also, label and attach copies of data collection tools at the end of this Initial Review Request.

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c) *Procedures*. Provide a chronological description of the experience of being a participant in this study. For archival data, describe how the data is secured, stored, and used.
d) Indicate which procedures and treatments are associated with the present study and those which are not part of the study (i.e., pre-existing programs, interventions, or classroom exercises).

4. SECONDARY ANALYSIS OF EXISTING DATA.

The specific information is necessary when identifiable data about human subjects will be obtained. Data are identifiable if they include direct or indirect identifiers such as name, e-mail address, UID Number, race, gender, nationality, age etc.

a) List source of the data and an explanation of why the data were originally collected.
b) Describe in detail the data you plan to access and analyze.
c) Indicate the requirements of the data supplier and how access to the data will be granted or obtained. If access to the data is governed by a data use agreement, provide a copy of the agreement.
d) Describe procedures that will protect data you are given access.

5. INVESTIGATOR QUALIFICATIONS

a) Describe the lead investigator's qualifications and experience in conducting this particular type of research.
b) If physical or psychological assessments are being administered who will administer the assessment and score the results and what are their qualifications for doing so? Is the training in human subject protection of those administering assessments adequate?

6. HUMAN SUBJECTS

a) **Characteristics.** Describe the characteristics of the participant population. Include the age range(s), gender, ethnicity, health status, any physical, mental, cognitive or emotional limitations, and any other relevant variables.
b) **Vulnerable Populations**. Indicate if subjects include students, prisoners, pregnant women or any other class of subjects that might be especially vulnerable and require special consideration.
c) **Pre-existing relationship to subject pool**. If subjects are students, describe the relationship between students and researcher. If there is a pre-existing relationship between the researcher and the subject pool, please describe that relationship in detail.
d) **Selection.** Describe criteria for inclusion and exclusion of subjects in the study**.** Provide a detailed explanation for each exclusion and inclusion criterion.
e) **Justification for the proposed sample size.** This number helps reviewers understand the expected sample size. Please explain why this number was chosen for your sample size. Any increases to sample size require a modification to the study.

7. RECRUITMENT.

a) Describe how subjects will be identified and recruited.
b) **Attach all materials to be used in recruitment.** Provide detailed description and example where relevant of any material presented to potential participants prior to their receipt of the informed consent/assent documents. Include advertisements, postings on social media, posters, scripts for radio/TV, other electronic ads, scripts for verbal recruitment, copies of email recruitments, and any text that will be provided to potential participants. It should be clear in all recruitment materials that you are conducting research. See Sample Recruitment flyer on IRB website.

8. SUBJECT PAYMENT

a) Describe any economic or other incentives for participation including reimbursement for time and travel.
b) If study participation requires subject to complete multiple sessions, payments must be pro-rated over

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the course of the study. (Example: In a study where subjects are paid $50 per session, Tom completes only two sessions, then he should be paid $100 for his participation)

c) If the study incentive involves earning course credit, list alternative ways to earn the same credit.

9. POTENTIAL RISKS.

a) Describe all potential risks: physical, psychological, social, legal or other associated with each procedure. Assess the probability, severity, potential duration and reversibility of each risk.

b) Identify those risks that are minimal and those which are more than minimal.

c) Describe the procedures used to minimize any potential risks.

10. POTENTIAL BENEFITS.

a) Describe the direct potential benefits to the subject. If there are none, this should be so stated.

b) Describe the potential societal benefits of the study in terms of human health/welfare, the advancement of knowledge or the good of society.

11. DIFFERENTIAL EVALUATION OF RISKS AND BENEFITS

Justify the research study based on your evaluation of the risk/benefit assessment. When composing this section, imagine you are standing in front of a panel of researchers who are all skeptical about your research. Your task is to reassure them that the benefits of your research outweigh the risks.

12. PRIVACY

The research proposal should outline strategies to protect privacy, including how the investigator will access participant information.

In developing strategies for the protection of subjects' privacy, consideration should be given to:

- The methods used to identify and contact potential subjects.
- The settings in which an individual will be interacting with an investigator.
- The appropriateness of all personnel present for research activities.
- The methods used to obtain information about subjects.
- The nature of the requested information.
- Information that is obtained about individuals other than the "target subjects," and whether such individuals meet the regulatory definition of "human subject" (e.g., a subject provides information about a family member for a survey).
- Privacy guidelines developed by relevant professional associations and scholarly disciplines.
- How to access the minimum amount of information necessary to complete the study.

13. CONFIDENTIALITY

The research proposal should outline in detail the strategies to maintain confidentiality of identifiable data, including controls on storage, handling, sharing of data as well as eventual destruction of identifiable data including signed consent forms.

14. COLLABORATION, ENGAGEMENT & SPONSOR RELATIONSHIPS

a) Describe all collaborative relationships necessary to complete your research. Include letters of support from the collaborator(s). This letter must come from a person with director-level authority within the collaborating institution. When the collaborator has an Institutional Review Board, please include a copy of the IRB application sent to collaborating institution.

b) Indicate in your study when U of M IRB approval must be issued before the collaborator will commit to the study.

c) Specify what data will be provided to the collaborator(s) and sponsor(s).

15. PROPOSAL

If your study is sponsored, please insert a copy of the funded proposal under this section.

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16. INFORMED CONSENT.

Informed consent to participate is required of all research involving human subjects and must include the elements listed below. Such consent must be given by the subject and parent/guardian if the subject is under the age of eighteen (18) years. Voluntary and fully informed consent must be obtained and documented in writing unless a waiver is requested and granted. If you plan to obtain consent in another fashion, please provide detailed information on how consent will be obtained and documented.

Investigators can request a "Waiver of Written Documentation of Consent" or "Waiver of Certain Elements of Consent" via forms located on the IRB website.

Also, templates for Informed Consent, Parental Consent, and Children's Assent forms are available on the IRB website.

Required Elements of Consent

a) State that the study involves research.
b) Explain the purpose of the research. The purpose should re-state the study goal in language appropriate for the study population.
c) Describe the procedures to be followed.
d) Indicate the expected time the subject will need to dedicate to the study.
e) Identify any procedures that are experimental, and explain the standard treatment if the study involves an experimental drug, substance, or intervention.
f) Describe any foreseeable risks or discomforts.
g) Describe the benefits to the subjects or others that may result from the research.
h) Describe the extent, if any, to which confidentiality of records identifying the subject will be maintained.
i) Explain that participation is voluntary and that the subject may discontinue at any time. Also state whether or not the participant may withdraw their data if they discontinue and how the data will be destroyed if applicable.
j) Explain whom to contact with questions about the research, such as the investigator and faculty advisor, if applicable.
k) Explain whom to contact for questions about subjects' rights. The following information can be listed to satisfy this requirement: Chris Whitehead, Administrator for the Institutional Review Board for the Protection of Human Subjects can be contacted via e-mail at irb@memphis.edu or by phone at 901-678-2705.
l) Describe any payment or incentive that will be offered to each subject and the conditions under which they will receive partial or no payment. If there is no payment/incentive, there is no need to mention it.
m) State that The University of Memphis does not have any funds budgeted for compensation for injury, damages, or other expenses.
n) Include, if study subjects are adults, a statement affirming that the subject is 18 or over above the study signature line.
o) Subject Signature must include a line for the subject to print their name, sign their name, and indicate the date consent was obtained.

Additional Points to Consider

- Is the consent form at the appropriate reading level and does it use vocabulary that potential subjects will understand?
- Is the language culturally appropriate? This includes whether there are social or cultural issues limiting free choice to participate in research and, if so, how will you address them?
- If your study involves a focus group, you cannot promise total anonymity or confidentiality because the

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participants are under no such duty. Please adjust the language in your consent document to properly inform potential study subjects.

- Any requests for Waivers must be submitted with the IRB submission to which they apply. In order to be considered, waivers must be requested with the applicable form from the IRB Webpage.

Please send the completed form via email to irb@memphis.edu.